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510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92."

"The assigned 510(k) number is: K023189 *."*

1. Submitter Information: **September 20, 2002**

B. Braun Medical Inc.
1601 Wallace Drive Ste. 150
Carrollton, TX. 75006
(972) 245-2243 ext. 206

Contact Person: Ms. Linda Morgan
Regulatory Affairs Specialist
Phone: 972.245.2243 ext. 339
FAX: 972.245.1612

2: Name of Device: **Infusion Pump**

Trade Name: **Vista™ basic with *fm system***
(formerly known as the Infusomat P K003029)

Classification Name: **Class II, 80FRN**
21 CFR 880.5725

3: Predicate Device:

The predicate devices that B. Braun Medical Inc. is claiming substantial equivalence[1] to are the Horizon Outlook™ and the Alaris Medley™ Patient Care System. The Horizon Outlook™ is marketed by B. Braun Medical under cleared 510(k) K994375. The Medley™ Patient Care System is marketed by Alaris under cleared 510(k) 950419. This substantial equivalence claim is intended for Food, Drug and Cosmetic Act purposes only. There are no new issues of safety or effectiveness raised by the Vista™ basic with *fm system*.

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[1] The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

4: Description of the Subject Device:

The Vista™ basic is an electrical external infusion pump intended to provide accurate infusions of parenteral and enteral fluids. The addition of the ***fm system*** will enhance the use of the Vista™ basic by allowing the user greater flexibilty in the administering and monitoring of a patients infusion status. Used as a complete system the Vista™ basic with ***fm system*** introduces some additional features to aid the clinician in fluid delivery and maintenance.

These features include the addition of a barcode reader to minimize the potential for programming errors, an external power source to reduce the number of electrical outlets required at the bedside, and the convenience of a large interactive monitor that displays the status of all Vista™ basics being used on one particular patient. This monitor also incorporates the use of a drug library, makes calculations based on user input. In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Inc. intends to introduce into interstate commerce the Vista™ basic with ***fm system***.

The infusion pump contains the following hardware assemblies: linear peristaltic pumping mechanism assembly, power supply assembly, pole clamp assembly, display assembly, and electronics assembly. The power supply cord can be mounted and removed from a receptacle in the rear of the pump. The battery power supply consists of a 12V rechargeable battery. The display subassembly contains an LCD display and a keypad used to input data into the pump as well as to present pump status and information to the user.

The electronics subassembly contains all of the electronics in the pump, including the microprocessors that run the software. The electronics subassembly also contains communications electronics that will allow the pump to transmit and receive messages to and from external devices, including personal computers and hospital monitoring systems.

The software provides communication capabilities from the pump to external communication devices. This includes transmission of the following information: Operation / Alarm Log, pump status and pump configuration / calibration data.

The software also provides communication abilities from external devices to the pump. This feature is only accessible by a trained Biomedical Technician. Programming of the pump is to be performed by trained Biomedical professionals.

5: Intended Use of the Subject Device:

The intended use of the Vista™ basic with ***fm system*** remains to provide accurate and continuous flow of parenteral, including blood, and enteral fluids to the patient. The addition of the ***fm system*** extends the abilities of the Vista™ basic and creates a versatile system that will enhance the administration and management of infusion therapy. The ***fm system*** may be used in a variety of configurations depending on the level of needs of the healthcare facility.

The new incorporation of a barcode reader and programmable dosing limits are intended to aid in medication error reduction by decreasing the steps necessary to program an infusion and to alert the clinician when dose amounts are not within facility defined parameters.

The Vista™ basic with ***fm system*** is intended for but not limited to use in the hospital and/or other healthcare facilities. The Operation Manual is intended to reinforce the teaching given to the user by a trained healthcare professional or an authorized B. Braun Medical Inc. representative. A trained Biomedical Technician must perform a full set-up of the pump before use in a clinical setting.

6: Technological Characteristics of the Subject Device

The subject device, Vista™ basic with ***fm system*** is substantially equivalent to the predicate devices, the Horizon Outlook™ and the Alaris Medley™ Patient Care System. The subject and predicate devices are similar in design, material composition, components, manufacturing process, intended use and labeling. There are technological differences between the subject and predicate device, however, these differences do not raise new issues of safety and effectiveness. The substantial equivalence claim between the subject and predicate device is supported by the information and data provided in this 510(k) submission. This includes the following information:

- Description of the subject and predicate devices.
- Intended use of the subject and predicate devices.
- Material composition of the subject and predicate devices.
- Labels and labeling for the subject and predicate devices.

- Comparison tables of attributes and specifications of the subject and predicate devices.
- Subject device customer functional specification.
- Subject device system and software hazard analysis.
- Subject device system and software requirements.
- Subject device system and software test plans.
- Subject device system and software trace matrix.

7: Signature of Applicant

B. Braun Medical Inc.
Linda Morgan RN, BSN
Regulatory Affairs Specialist

Linda Morgan RN 9/20/02

Signature Date

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Attachment

Predicate Device Description

The predicate device for the barcode that B. Braun Medical is claiming substantial equivalence to is the Horizon Lite. The Horizon Lite is marketed under cleared 510(k) K994375. B. Braun Medical Inc. submitted the device under the name Horizon Lite and is now marketed as the Horizon Outlook™.

The predicate device for the ***fm system*** that B Braun Medical is claiming substantial equivalence to is the Alaris Medley™ Patient Care System, marketed under cleared 510(k) K950419.

Comparison of the Subject and Predicate Barcode

The operation of the subject and predicate barcode label generators and readers are similar in that both require the scan of and medication name and dosage/rate information. Both systems require the clinician to view and validate the entry.

The Vista™ basic with ***fm system*** and the Horizon Outlook™ are similar in that they are both infusion pumps that that can accommodate barcode scanned data. They are similar in that they are both computer controlled, external, volumetric, infusion pumps composed of injection molded thermoplastic components. The components of the Vista™ basic and the Horizon Outlook™ are all non-solution contact parts. The subject and predicate devices are similar in their intended use, that is, to deliver fluids at a controlled rate.

The subject and predicate devices are similar in that they are both intended for use in the hospital or health care settings to control the infusion rate of parenteral fluids to patients.

Comparison of the *fm system* and Medley™ Patient Care System

The ***fm controller*** and Alaris Medley™ are similar in that they are both used in conjunction with infusion pumps or pumping modules that can be controlled while connected to them. Both the subject and the predicate devices have a large interactive screen that displays pump status. Both subject devices incorporate drug list, calculations and dosing limits.

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The subject and predicate devices are different in that the ***fm system*** is an accessory, to the Vista™ basic. The Vista™ basic is a stand alone infusion pump and can function without the ***fm system*** whereas the pumping modules of the Alaris Medley™ cannot operate when removed from the programming module.

A table further identifying the similarities and differences between the ***fm controller*** and Alaris Medley™ Patient Care System is listed below. The table compares the features and specifications of the devices. The contents of these tables support the substantial equivalence claim between the ***fm controller*** and the Alaris Medley™.

A. Table of Comparisons

SPECIFICATIONS AND FEATURES		
Attribute	**Subject Device-Vista™ basic with fm system**	**Predicate Device-Alaris Medley™ PATIENT CARE SYSTEM**
Control pump activities from monitor	yes	yes
Pump or pumping module can function on its' own	yes	no
Barcode capabilities	yes	no
Drug calculation abilities	yes	yes
Drug library	yes	yes
Dosing limits	yes	yes
Display all pumps attached to monitor	yes	yes
Communication port	yes	yes
Print screen data	yes	yes
Provide AC power to pumps	yes	yes
Materials	Injection Molded Thermoplastics	Injection Molded Thermoplastics
Visual Display	Digital LCD	Digital LCD

Material Composition

The material composition of the subject and predicate devices are similar in that they are both composed of injection molded thermoplastics. None of the components of the pump or accessories are in contact with any solution delivered by the pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Ms. Linda Morgan
Regulatory Affairs Specialist
B. Braun Medical Incorporated
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006

Re: K023189
Trade/Device Name: Vista™ Basic with *fm system*
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: December 17, 2002
Received: December 20, 2002

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

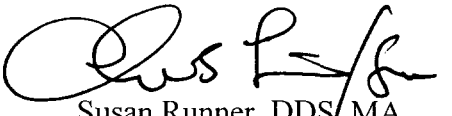
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known) K023184

Device Name: Vista™ basic with *fm system*

Indications For Use:

The intended use of the Vista™ basic with *fm system* is to provide accurate and continuous flow of parenteral, including blood, and enteral fluids to the patient.
The addition of the *fm system* extends the abilities of the Vista™ basic and creates a versatile system that will enhance the administration and management of infusion therapy. The *fm system* may be used in a variety of configurations depending on the level of needs of the healthcare facility.

The new incorporation of a barcode reader and programmable dosing limits are intended to aid in medication error reduction by decreasing the steps necessary to program an infusion and to alert the clinician when dose amounts are not within facility defined parameters.

The Vista™ basic with *fm system* is intended for but not limited to use in the hospital and/or other healthcare facilities. The Operation Manual is intended to reinforce the teaching given to the user by a trained healthcare professional or an authorized B. Braun Medical Inc. representative. A trained Biomedical Technician must perform a full set-up of the pump and system before use in a clinical setting

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cusenta
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023184